

### **REMARKS**

These amendments and remarks are being filed in response to the non-final Office Action mailed November 13, 2008 (the "Office Action"). At the time of the Office Action, claims 12-16, 18, 19 and 23-30 were pending, with claims 15 and 26-28 withdrawn from consideration. The Office Action rejected all of the claims under 35 U.S.C. §103(a). The rejections and response thereto are set forth fully below.

#### **Rejection Under 35 U.S.C. § 103**

Claims 12, 13 (in part), 14, 16, 18-19, 23-25 and 29-30 were rejected under 35 U.S.C. § 103, as being unpatentable over U.S. Patent No. 5,122,418 issued to Nakane *et al.* (hereinafter "Nakane") in view of U.S. Patent No. 4,142,521 issued to Konikoff (hereinafter "Konikoff"). The claimed composition addresses the problem of producing a cosmetic composition that improves the absorption of vitamins and supplements (*e.g.* creatine) through the skin. Prior art approaches addressing this problem sought to utilize mixtures of vitamins and minerals with compounds known to improve skin absorption, such as surfactants and phospholipids. Such compounds are themselves capable of passing through the skin surface. Thus, unlike the prior art, the claimed composition provides improved skin absorption using particles that do not pass through the skin surface.

The skin is a structurally complex, relatively thick membrane that is designed to provide a barrier function. Molecules, such as vitamins and supplements, moving from the skin surface into and through intact skin must first penetrate the stratum corneum and any material on its surface. Such molecules must then penetrate the viable epidermis, the papillary dermis, and the capillary walls into the blood stream or lymph channels to be absorbed through the skin and into the organism. Molecules, such as vitamins and creatine, must overcome a different resistance to penetration in each type of tissue. For this reason, absorption of vitamins and supplements is substantially less than 100%. Transport through the skin membrane is thus a complex phenomenon. However, it is the cells of the stratum corneum, which present the primary barrier to absorption of topical compositions containing active agents, such as vitamins and creatine. In contrast, the skin barrier function is severely compromised when dealing with an open wound and healing is a different mechanism entirely.

With this background, Applicants wish to review the claimed invention as recited in claim 12, which recites:

12. (previously presented) A cosmetic composition containing an electret material which comprises

0.1 to 10% by weight of a cosmetically acceptable, solid electret material with a particle size of 0.05 to 100  $\mu\text{m}$ , which electret material has an induced permanent dipole moment and a permanent electric dipole field with a field strength of 500 to  $10^7 \text{ Vm}^{-1}$ , the percentage data being relative to the total weight of the composition,

furthermore comprising cosmetic carrier substances, cosmetic auxiliaries, further cosmetic active agents or a mixture thereof, and

a cosmetic active agent, selected from the group consisting of

a product containing Vitamin A that is added in an amount to impart at least 0.1% Vitamin A to the overall composition,

a product containing Vitamin E that is added in an amount to impart at least 0.1% Vitamin E to the overall composition,

a product containing Vitamin B that is added in an amount to impart 0.1 to 3 wt-% Vitamin B to the overall composition,

a product containing creatine that added in an amount to impart 0.1 to 3% creatine to the overall composition, or

a mixture thereof.

The claimed cosmetic composition is drawn to a cosmetic composition that, when compared to a cosmetic composition that does not include the claimed electret materials, exhibits improved absorption of Vitamin A, Vitamin B, Vitamin E and Creatine through the skin. *See* Specification, paragraph [0017]-[0019]. The claimed cosmetic composition includes 0.1 – 10 wt-% electret material and specified amounts of Vitamin A, Vitamin B, Vitamin E, creatine or a combination thereof. These specific amounts and ratios of ingredients cause skin absorption of the relevant vitamins and supplements to increase by at least 25%. *See* Specification, paragraphs [0017]-[0019]. This improved absorption of cosmetically active ingredients was a surprising result to the Applicants and was not disclosed or suggested by any of the cited references, whether alone or in combination.

As described above, it was expected that improved skin absorption could be achieved by utilizing a compound, such as a surfactant, that can itself pass through the skin. In contrast to the expected solution, Applicants have discovered that improved absorption can be achieved using

0.05-100 $\mu$ m electret particles in very close contact with skin cells where each individual electret particles have a dipole moment of 500-10<sup>7</sup> V/m. *See* Specification, paragraph [00018]-[00020].

While not wishing to be bound by theory, it is believed that the use of small particles causes dipole-dipole interactions between the dipoles of the individual micro-scale electret particles and the natural dipoles of the skin, such as cell membranes, proteins, peptides, amino acids, electrolytes, *etc.* The close contact between the skin and the individual micro-scale electret particles enables dipole-dipole interactions which are possible because of the dimensions of the particles and their direct contact with the skin. Prior to the filing of the instant application, this approach was not known to those of skill in the art.

Applicants also note that the disclosure of Konikoff is substantially limited by the different structure utilized by the claimed cosmetic composition. Konikoff discloses that the generation of an electrostatic field having a strength of about  $-2.0 \times 10^{-9}$  coulombs/cm<sup>2</sup> promotes soft tissue wound repair. *See* Konikoff, col. 6, ln. 29-31; col. 8, ln. 3-9 & 51-54. This electrical field strength is produced using an electret foil strip.

In contrast to the foil strips of Konikoff, the claimed cosmetic compositions include solid electret materials with a particle size of 0.05 to 100  $\mu$ m. Because the orientation of the dipoles in the claimed composition is random, the claimed cosmetic composition comprising solid electret particles does not produce a average field strength. In fact, there is a zero net electrostatic field produced by the claimed cosmetic composition.

A person of ordinary skill in the art could not have expected to produce an emulsion of electret particles with an electrostatic field strength of about of about  $-2.0 \times 10^{-9}$  coulombs/cm<sup>2</sup>. This is because, such an electrostatic field strength does not exist in an emulsion of randomly oriented micro-scale electret particles. Because of these differences in structure and electrostatic field strength, a person of ordinary skill in the art would not expect electret particles to have the same effect as the foil strip electrets disclosed by Konikoff.

Surprisingly, Applicants have discovered that when the emulsion is applied to the skin, the intimate contact between the 0.05 to 100  $\mu$ m electret particles and skin constituents causes improved absorption of vitamins and other active agents through the skin. It is believed that this is caused by the microscopically close interactions of the electret dipoles with the natural dipoles of skin constituents, *e.g.*, cell membranes, proteins, peptides. This is dependent on the particle

size and the particles having a electric dipole field with the claimed field strength, which is measured in Volt meters, not Coulombs per square centimeter as in Konikoff. Because of the substantial structural differences, the requisite electrostatic field disclosed by Konikoff simply is not present in the claimed cosmetic composition. Accordingly, Applicants respectfully submit that there are substantial differences between the application of Nakane and Konikoff that would prevent one of ordinary skill in the art from expecting that the use of micro-scale electret particles (no electrostatic field) would have the same effect as the electret strip (electrostatic field stimulating would healing) disclosed in Konikoff. Accordingly, Applicants respectfully request that the rejection based on the combination of Nakane and Konikoff be withdrawn.

Applicants now turn to the "Response to Arguments" section, in which the Office Action asserts that the improved skin absorption is an intended use that is entitled to little patentable weight. Applicants respectfully submit that the improved skin absorption is a property of the claimed cosmetic composition that is entitled to significant patentable weight as an unexpected property. In this regard, Applicants direct the Examiner to *In re Chupp*, 816 F.2d 643 (Fed. Cir. 1987), which is discussed in more detail below.

The Examiner also cites *In re Spada*, 911 F.2d 705, 709 (Fed. Cir. 1990) for the assertion that "A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the disclosed properties are necessarily present." See Office Action, page 5. The Office Action then states that the "burden is shifted to the applicant to show that the *prior art product* does not inherently possess the same properties as the ***instantly claimed product***." See *id.* (emphasis added).

In addition to the distinctions related to the electrostatic field discussed above, Applicants respectfully submit that the Examiner's assertion of inherency using *In re Spada* is not applicable to the current context because the claimed composition is not disclosed by any individual prior art reference. Clearly, the Office Action is relying on a combination of multiple references, *i.e.*, Nakane and Konikoff, in order to assert the instant obviousness rejection. Thus, Applicants respectfully assert that the rationale of *In re Spada* does not apply to the instant rejection, because the instant rejection is an obviousness rejection based on two references, not an anticipation rejection. *In the instant case, there is nothing in any of the cited references that discloses the claimed cosmetic composition as a whole (where inherency could be applicable), or that the*

*claimed cosmetic composition would exhibit unexpectedly improved absorption of cosmetic active ingredients (which would be necessary for a conclusion of obviousness).*

In *In re Spada*, applicant Spada claimed a product, a pressure sensitive adhesive composition comprising a water-based latex comprising a normally tacky polymer with a  $T_g$  of 0°C or less, where the polymer included specific amounts of two classes of monomers. *See In re Spada*, 911 F.2d at 706-07. A third class of monomer was included in preferred embodiments. *See id.* at 707.

The examiner cited the Smith patent against the Spada application as part of a one reference rejection under 35 U.S.C. §102/§103. *See id.* Like the Spada claims, Smith disclosed a product, a water-based latex comprising polymers used as binding agents. *See id.* The polymers disclosed in Smith included the claimed amounts of the two classes of monomers, as well as the preferred amount of the third monomer. *See id.* In addition, "Spada incorporated by reference the entire disclosure of the Smith patent, as showing polymerizable functional monomers suitable and preferred for use in the Spada polymers, and the preparation of these monomers." *See id.* The Board sustained the Examiner's rejection under 35 U.S.C. §102/§103, *see id.*

In the relevant portion of the decision, ***the Federal Circuit analyzed the rejection as an anticipation rejection***, because the end products disclosed in Smith were identical to the subject matter of the Smith claims. *See id.* at 707-08. The Federal Circuit approved of the Board's conclusion that "the polymerization by both Smith and Spada of identical monomers, employing the same or similar polymerization techniques, would ***produce polymers having the identical composition.***" *See id.* at 708. The Federal Circuit concluded that it was proper to conclude that the Spada claims ***lacked novelty*** because of the "virtual identity of monomers and procedures [for making the polymers]," *See id.*, and sustained the rejection because Spada was unable to demonstrate that the conclusion that the products were the same. *See id.* at 709.

Applicants contend that *In re Spada* is relevant to anticipation rejections under 35 U.S.C. §102 or single reference rejections under 35 U.S.C. §102/103, but irrelevant to the multi-reference obviousness rejection at issue in the Office Action. This is further supported by *In re Rijckaert*, 9 F.2d 1531, 1534 (Fed. Cir. 1993), where the Federal Circuit stated that "Obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established." *See* MPEP 2141.02.V. Because the instant rejection is a

multiple reference obviousness rejection, *In re Rijckaert* applies to the exclusion of *In re Spada*. The clear distinction is that the *In re Spada* anticipation reference disclosed every step and ingredient necessary to produce the claimed composition, *i.e.*, the claimed subject matter was already disclosed. In contrast, the instant rejection is based on a combination that was never disclosed by any individual prior art reference. Quite simply, the arguments in the Office Action are based on a misinterpretation of *In re Spada* that flies in the face of both *In re Rijckaert* and *In re Spada*.

Because the properties are not inherent to compositions disclosed by any one of the cited references, proper consideration of the instant claims requires consideration of the unexpectedly improved absorption of cosmetic actives exhibited by the claimed cosmetic compositions. The Office Action asserts that the evidence of unexpectedly improved absorption of cosmetic actives is merely an intended use and refuses to give this property patentable consideration. *See* Office Action, page 6-7. Applicants respectfully submit that the relevant property, the improved absorption of cosmetic active ingredients, is ***an intrinsic property of the claimed composition*** (but not of a composition disclosed by any single reference). As is evident from the Federal Circuit's decision in *In re Chupp*, 816 F.2d 643 (Fed. Cir. 1987), intrinsic properties of a claimed composition must be considered for patentability of a composition and are sufficient to overcome an obviousness rejection. *See* discussion below. As evident from *In re Rijckaert*, "Obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established." *See Rijckaert*, 9 F.2d at 1534; MPEP 2141.02.V. Thus, a conclusion of obviousness is precluded by the fact that there is nothing in the cited references that discloses or suggests the unexpectedly improved absorption of cosmetic actives exhibited by the claimed compositions.

In *In re Chupp*, the Federal Circuit held that evidence that a compound or composition possesses superior and unexpected properties in one of a spectrum of common properties can be sufficient to rebut a *prima facie* case of obviousness. *See In re Chupp*, 816 F.2d at 646; MPEP 2145. The claims in *In re Chupp*, were drawn to a compound for use as a selective herbicide with unexpectedly superior herbicidal efficacy for soybeans and corn, but average results for other crops. *See id.* at 644. The prior art was a homolog of the claimed compound and was disclosed as being a selective herbicide for crops generally.

The Federal Circuit noted that the claimed compound's "superior activity in corn and soybeans is a new and unexpected property," *In re Chupp*, 816 F.2d at 645. The Commissioner argued that the claimed compound provided average selective herbicidal activity for many crops and poor herbicidal activity for others. The Federal Circuit responded to this argument by concluding that the fact that a compound or composition possesses superior and unexpected properties in one of a spectrum of common properties was sufficient to rebut a *prima facie* case of obviousness. *See id.* at 646.

From *In re Chupp*, two propositions are clear. First, the intrinsic properties of a claimed compound or composition should be given patentable weight. *See In re Chupp*, 816 F.2d at 644-646. Thus, evidence of a composition exhibiting unexpectedly improved skin absorption of cosmetic active agents cannot be dismissed as an intended use. Second, evidence of such unexpected results in one of a spectrum of common properties was sufficient to rebut a *prima facie* case of obviousness. *See In re Chupp*, 816 F.2d at 646.

In the instant case, the presence of electret materials in the claimed cosmetic composition produces unexpectedly improved absorption of cosmetic active agents. Arguments of inherency using *In re Spada* are simply not applicable because the rejection is based on a combination of references, not a single reference.

With respect to the arguments that the claimed absorption properties are merely an intended use, in *In re Chupp* the Federal Circuit clearly uses evidence that a composition of matter exhibits unexpectedly improved herbicidal activity with respect to two plant varieties as evidence sufficient to overcome an obviousness rejection. Clearly, the Federal Circuit precedent does not support a conclusion that intrinsic properties of a claimed composition, such as the improved absorption properties of the claimed cosmetic composition, are merely intended use limitations that are not entitled to patentable weight.

The unexpected absorption properties of the claimed composition are neither disclosed nor suggested by the cited references. As explained by *In re Rijckaert*, 9 F.2d 1531, 1534 (Fed. Cir. 1993), "Obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established." *See* MPEP 2141.02.V. In addition, the Federal Circuit in *In re Chupp* concluded that the fact that a compound or composition possesses superior and unexpected properties in one of a spectrum of common properties was

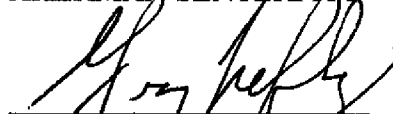
sufficient to rebut a *prima facie* case of obviousness. *See In re Chupp*, 816 F.2d at 646. Thus, a conclusion of obviousness cannot be supported considering the fact that there is nothing in the cited references that discloses or suggests that the claimed cosmetic compositions would exhibit unexpectedly improved absorption of cosmetic active agents. Accordingly, Applicants respectfully submit that all claims are drawn to patentable subject matter.

### **Conclusion**

If anything further is necessary to properly respond to the Restriction Requirement, Applicants respectfully ask that the Examiner contact Greg Lefkowitz at 561-671-3624 (direct line). No fees are believed to be due for submission of this Response; however, the Commissioner is hereby authorized to charge any underpayment or credit any surplus to Deposit Account No. 50-0951.

Respectfully submitted,

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